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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/869,136 | 07/20/2001 | John D Fraser | 3911-8 | 1247 |

7590 11/18/2003
Y. ROCKY TSAO
FISH AND RICHARDSON P.C.
224 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

MINNIFIELD, NITA M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1645

DATE MAILED: 11/18/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,136

Applicant(s)

FRASER ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 3-13 and 15-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 14 and 31 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☒ Claim(s) 3-13 and 15-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed August 18, 2003 is acknowledged and has been entered. Claim 14 has been amended. New claim 31 has been added. Claims 1, 2, 14 and 31 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. This application contains claims 3-13 and 15-30 drawn to an invention nonelected with traverse in Paper No. 11 (12/09/02/). A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
4. Claim 14 is objected to because of the following informalities: there is no period at the end of the sentence. Appropriate correction is required.
5. 35 U.S.C. §101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1, 2 and 31 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter. Claims 1, 2 and 31, as written, do not sufficiently distinguish over proteins and nucleic acids, as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified" or similar claim language, assuming the specification support and enablement for such claim language. See MPEP 2105.

7. Claims 1 and 2 (and now claim 31) are rejected under 35 U.S.C. 102(b) as being anticipated by Kamezawa et al (Infection and Immunity, 1997).

The claims are directed to a superantigen, SMEZ-2, which has an amino acid sequence of SEQ ID NO: 2 or a functionally equivalent variant thereof.

Kamezawa et al discloses a SMEZ (streptococcal mitogenic exotoxin Z) superantigen from *Streptococcus pyogenes* (abstract). The prior art discloses that these superantigens have a molecular weight range of 25 to 30 kD, a pI of 7 and biological activities include mitogenicity and they act as superantigens to stimulate T cells to produce cytokines (p. 3828, column 1 and materials and methods). Kamezawa et al discloses the amino acid sequence of the superantigen (see figure 5, p. 3832; p. 3831).

The claimed polypeptide appears to be disclosed in the prior art. The prior art polypeptide appears to be the same as claimed. The prior art polypeptide

appears to have the same functions (i.e. mitogenic activity, stimulates T cell Receptors) as set forth by Applicants.

Since the Patent Office does not have the facilities for examining and comparing applicants' polypeptide with the polypeptide of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed polypeptide and the polypeptide of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The rejection of claims 1, 2 and now 31 under 35 U.S.C. § 102(b) as anticipated by Kamezawa et al is maintained. This rejection is maintained for essentially the same reasons as the rejection of claims 1 and 2 under this statutory provision, as set forth in the last Office action. Applicants' arguments filed August 18, 2003 have been fully considered but they are not deemed to be persuasive. Applicants have asserted that in Figure 1 of the specification Applicants have aligned the sequence of SMEZ-2 against the sequence of SMEZ taught in Kamezawa et al and that these two sequences differ in 17 different amino acid residues. Applicants have asserted that the two superantigens also differ in their potencies to stimulate peripheral blood lymphocytes, specificities to enrich TCR VB and abilities to bind MHC Class II molecules. However, it is noted that these limitations (potencies to stimulate peripheral blood lymphocytes, specificities to enrich TCR VB and abilities to bind MHC Class II molecules) are not set forth in the claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. potencies to stimulate peripheral blood lymphocytes, specificities to enrich TCR VB and abilities to bind MHC Class II molecules) are

not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, with regard to the differences in the amino acid sequences, it is noted that the claims recite a SMEZ-2 superantigen having an amino acid sequence of SEQ ID NO: 2 *or* a functionally equivalent variant. It would appear that the superantigen taught in Kamezawa et al is a functionally equivalent variant of the superantigen having an amino acid sequence of SEQ ID NO: 2.

Kamezawa et al discloses the claimed invention, a superantigen, which has the same or similar characteristics as claimed. The superantigen or functionally equivalent variant in the prior art is believed to inherently possess properties which anticipates the claimed invention or if they are not the same the superantigen or functionally equivalent variant, would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the superantigen or functionally equivalent variant of the prior art is evidenced to meet the limitations of the claimed superantigen or functionally equivalent variant, in the absence of evidence to the contrary.

Since the Patent Office does not have the facilities for examining and comparing applicants' polypeptide with the polypeptide of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed polypeptide and the polypeptide of the prior art (i.e., that the polypeptide of the prior art does not possess the same material structural and functional characteristics of the claimed polypeptide). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*,

205 USPQ 594. Determination of characteristics, which vary depending on the method of analysis, such as enzymatic activity or other properties of the polypeptide, must be made by the same method under the same or analogous conditions to show differences that are not otherwise clearly apparent.

It is also noted that claims 1, 2, 14 and 31 are only examined with regard to SEQ ID NO: 2/SMEZ-2, not the other non-elected and withdrawn species ((SPE-G, SPE-H and SPE-J) that are still recited in the claims.

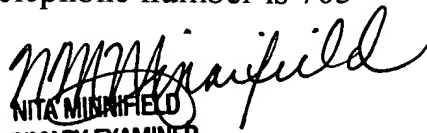
8. No claims are allowed.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


NITA MINNIFIELD
PRIMARY EXAMINER
AU 1645
11/16/03